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INTRODUCTION

Current antiretroviral therapy (ART) for the treatment of human immunodeficiency virus (HIV-1)-infected patients has the objective to provide control of viral load while simplifying drugs' administration. DRV/c is a fixed-dose combination including the protease inhibitor (PI) darunavir and the booster cobicistat (DRV/c), developed to reduce pill burden, making the PI easier to take and possibly avoiding mistakes in drug administration. In addition, it is important get insights from patients regarding satisfaction in their regimen and actual symptoms. To do so, Patients Reported Outcomes (PROs) are used.

STUDY DESIGN

"ST.O.RE" was an Italian prospective, multicenter non-interventional, cohort study carried on HIV-1-infected, adult out-patients, being in stable ritonavir-boosted ARV-treatment with PIs (either darunavir 800mg q.d.-based or other PIs) since at least 12 months and virologically suppressed (HIV-RNA < 50 copies/ml) since at least 6 months. Patients were offered to enter this study once their treating physician had considered they were eligible to be administered DRV/c-based treatment as per Summary of Product Characteristics. About 25 Infectious Diseases centers throughout enrolled 348 patients. Patients were observed (prospectively) for 48±6 weeks after starting DRV/c-based regimen. To assess patients' satisfaction on their regimen and actual symptoms, two validated PROs questionnaires were collected at pre-specified timepoints: HIV Treatment Satisfaction (HIV-TSQ) and HIV Symptoms Distress Module (HIV-SDM) (Figure 1).

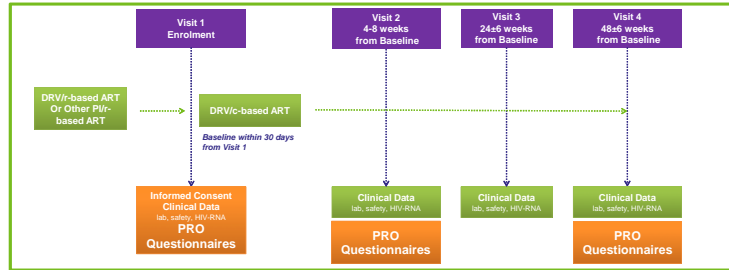


Figure 1: Study Design

OBJECTIVE

Here we describe the results obtained from HIV-TSQ and HIV-SDM questionnaires collected at baseline and after 48 weeks.

METHODS - PATIENT REPORTED OUTCOMES

HIV-TSQ is a 10-item instrument that is supported by evidence of good internal consistency reliability. The total score ranges from 0 to 60 (with every single question ranging from 0 to +6), with higher scores indicating greater treatment satisfaction. Two versions are available in order to collect patient status and change. Score change ranges from -30 to +30 (with every single question ranging from -3 to +3), with scores <0 and >0 indicating a decrease and increase in treatment satisfaction, respectively.

HIV-SDM was developed to assess 20 commonly experienced symptoms. Patients are asked about their experience of each of the symptoms during the past 4 weeks on a five-point Likert scale. Response options and scores range from (0) "I don't have this symptom" to (4) "I have this symptom and it bothers me a lot".

According to study protocol, final analysis at Visit 4 was performed to compare the score of HIV-SDM and HIV-TSQ questionnaires administered at Visit 4 versus Visit 1.

RESULTS

348 patients were enrolled in this study, 31% were females. In total, 250 patients (174 males and 76 females) provided both HIV-TSQ and HIV-SDM evaluable at both baseline and 48 weeks after. Of them, 200 (80%) came from a DRV/r-based regimen before starting DRV/c; the other 50 were treated with other PIs.

The main baseline characteristics of these patients are reported in the table below.

Patients Main Baseline Characteristics	Males (N=174)	Females (N=76)	Total (N=250)
Age - Mean (SD)	49 (10.2)	47.8 (8.5)	48.6 (9.7)
White race - N (%)	169 (97.1%)	70 (92.1%)	239 (95.6%)
HCV Seropositivity - N (%)	47 (27%)	19 (25.0%)	66 (26.4%)
Nr of years from the first HIV-1 positive test - Mean (SD)	12.6 (9.4)	17.3 (8.6)	14.0 (9.4)
Nr of years from the first ARV treatment - Mean (SD)	10.3 (7.6)	14.7 (7.2)	11.6 (7.7)
Nr of years from the first ARV treatment PI/r based - Mean (SD)	6.3 (5)	8.4 (5.4)	6.9 (5.2)
Nr of years from virosuppression - Mean (SD)	4.7 (4)	6.3 (4.6)	5.2 (4.2)
Pre-HAART viremia (copies/ml) - Mean (SD)	463939.3 (1282254)	142979 (262016.6)	373065 (1102728)
CD4 category C - N (%)	50 (28.7%)	20 (26.3%)	70 (28%)
CD4 Nadir (cell/mm ³) - Mean (SD)	207.8 (163.3)	226.3 (162.5)	213.2 (162.9)
Transmission			
Intravenous Drug User	32 (18.4%)	12 (15.8%)	44 (17.6%)
Homosexual/ Bisexual	70 (40.2%)	0 (0%)	70 (28%)
Heterosexual	47 (27%)	57 (75%)	104 (41.2%)
Other	3 (1.7%)	2 (2.6%)	5 (2%)

RESULTS - Continued

Improvement in patients' satisfaction was observed at Visit 4 (V4) compared with baseline (V1), as shown by the scores registered in HIV-TSQ (Figure 2).

At baseline a high percentage (67.2%) of patients declared to be "Very satisfied" (e.g. answering "+6" to the question "How satisfied are you with your current treatment?"), about their antiretroviral treatment PI/r-based (Figure 3). When asking the same question after 48 weeks, the satisfaction resulted improved, as shown in Figure 4 (positive scores mean satisfaction improvement).

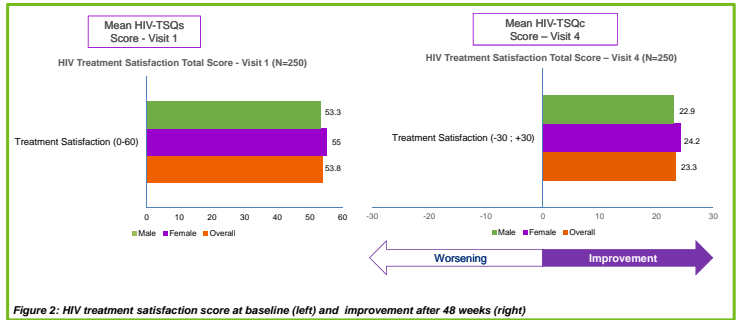


Figure 2: HIV treatment satisfaction score at baseline (left) and improvement after 48 weeks (right)

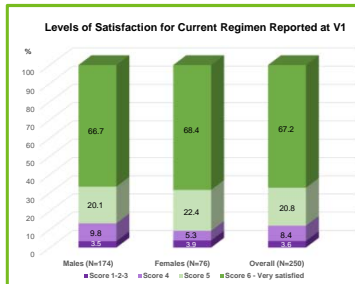


Figure 3: Percentages of patients reporting different levels of satisfaction regarding their ART at Visit 1 (V1)

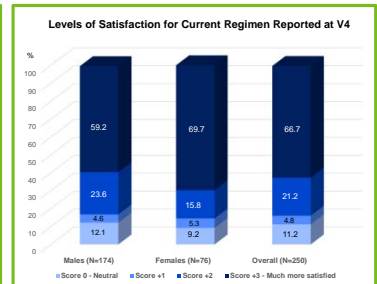


Figure 4: Percentages of patients reporting different levels of satisfaction regarding their ART at Visit 4 (V4)

The overall burden of symptoms, as shown by the HIV-SDM scores, decreased from V1 to V4: the mean value (SD) was 10.1 (9.9) at baseline, while it was 9.3 (10.4) at V4 (overall). Gender (p=0.0055) and SDM baseline score (p<0.0001) have statistically significant effect on SDM score at V4 (Figure 5).

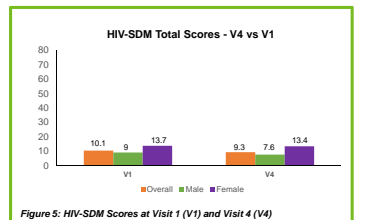


Figure 5: HIV-SDM Scores at Visit 1 (V1) and Visit 4 (V4)

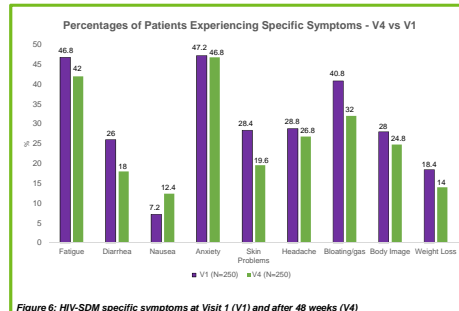


Figure 6: HIV-SDM specific symptoms at Visit 1 (V1) and after 48 weeks (V4)

Specific symptoms trends are reported in Figure 6. All symptoms, excepting nausea, decreased between V1 and V4 (p<0.0001, Chi-Square Test) thus showing the convenience of switching from PI/r-based treatment to DRV/c-based regimen.

CONCLUSIONS

The results here reported show that switching from a PI/r- to a DRV/c-based therapy led to an overall increase of patients' satisfaction and reduction of the burden of symptoms related to previous regimens, thus improving the patients' quality of life.

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